IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-1126 (LPS)
NEUMODX MOLECULAR, INC.,	)	
Defendant.	)	

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS NEUMODX'S AMENDED COUNTERCLAIMS FOR NON-INFRINGEMENT AND INEQUITABLE CONDUCT AND TO STRIKE NEUMODX'S AFFIRMATIVE DEFENSE OF INEQUITABLE CONDUCT

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Michael J. Flynn (#5333)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mflynn@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

William G. McElwain
David P. Yin
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Omar A. Khan
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

October 25, 2019

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Rules

I. NATURE AND STAGE OF THE PROCEEDINGS

In 2009, Plaintiffs Becton, Dickinson and Company and GeneOhm Science Canada, Inc. (collectively "BD"), acquired Plaintiff HandyLab, Inc. ("HandyLab"), after recognizing the potential of the emerging technologies being developed by HandyLab for use in bench-top devices for fast and early detection of disease. As part of that deal, BD gained an exclusive license to HandyLab's patents, including the Asserted Patents. *See* D.I. 1 ¶¶ 2, 10-11.[1] At the time, HandyLab's then-CEO Jeff Williams praised the "exclusive collaboration" with BD as "an important step forward in expanding the utility" of HandyLab's systems. D.I. 1, Ex. 7. Moreover, Williams said, the deal was "a good outcome for [HandyLab's] shareholders, [its] employees and for [its] customers." D.I. 1, Ex. 8. Ultimately BD used the patented technology to launch a successful next-generation molecular diagnostics platform, the BD MAX™ system. *See* D.I. 1 ¶¶ 12.[2]

In 2012, Williams founded a company called "Molecular Systems Corp.," which subsequently became Defendant NeuMoDx Molecular, Inc. ("NeuMoDx"). D.I. 1 ¶ 13. Sundaresh Brahmasandra, another co-founder of HandyLab who had subsequently taken the position of Vice President of R&D Assay Development at BD, later joined NeuMoDx. D.I. 1. The two HandyLab founders took the same patented technologies that they had sold and exclusively licensed to BD and used them to develop NeuMoDx's own line of molecular diagnostics products. Because NeuMoDx's products unlawfully infringe BD's patents, BD filed this action against NeuMoDx on June 18, 2019. D.I. 1.

NeuMoDx filed its answer and counterclaims on August 9, 2019. D.I. 8. BD filed a motion

[1] The "Asserted Patents" are U.S. Patent Nos. 8,273,308 ("'308 patent"); 8,703,609; 7,998,708 ("'708 patent"); 8,323,900 ("'900 patent"); 8,415,103; and 8,709,787. D.I. 1 ¶ 2.

[2] "Molecular diagnostics" is a term used to describe a family of techniques used to analyze biological markers in an individual's genetic code and to analyze how their cells express their genes. *See* "Molecular Diagnostics," *ScienceDirect*, *available at* https://www.sciencedirect.com/topics/medicine-and-dentistry/molecular-diagnostics (last accessed Sept. 13, 2019). These techniques are used to "identify or confirm genetic variants associated with diseases or that can serve as surrogate markers of disease." *Id*.

to dismiss NeuMoDx's counterclaims for non-infringement and inequitable conduct on September 13, 2019. D.I. 11. In response to BD's motion, NeuMoDx filed a first amended answer and counterclaims on October 4, 2019 amending its non-infringement and inequitable conduct counterclaims. D.I. 15.

As its First Amended Count, NeuMoDx again counterclaims for a declaratory judgment of non-infringement, in support of which NeuMoDx conclusorily asserts that:

> 10. NeuMoDx's Accused Molecular Diagnostic Products do not infringe [various claims of the Asserted Patents], either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of [those] patents.
>
> 11. NeuMoDx's Accused Molecular Diagnostic Products also do not infringe any do not infringe claims of the [Asserted Patents], either directly or indirectly, because [those] patents are invalid and thus cannot be infringed. (D.I. 15 at 15)

As its Third Amended Count, NeuMoDx repeats its counterclaim that BD's patent prosecution attorney, Ned Israelsen, committed inequitable conduct by including a boilerplate remark during the prosecution of the '708 patent. D.I. 15 at 19-23. NeuMoDx now also alleges that, during the prosecution of the '708 patent and the '900 patent, Israelsen "intentionally misled" the Examiner by arguing that a prior art reference did not disclose certain limitations of the '708 and '900 patents. D.I. 15 at 23-27. NeuMoDx incorporates the same inequitable conduct allegations in its Third Affirmative Defense. D.I. 15 at 9.

Plaintiffs renew their motion to dismiss NeuMoDx's amended non-infringement and inequitable conduct counterclaims under Federal Rule of Civil Procedure 12(b)(6), and also move to strike NeuMoDx's affirmative defense of unenforceability based on inequitable conduct under Federal Rule of Civil Procedure 12(f).

II. SUMMARY OF THE ARGUMENT

1. NeuMoDx's counterclaim for a declaratory judgment of non-infringement fails to satisfy

the *Twombly/Iqbal* standard because it is wholly conclusory and does not plead any specific facts, much less facts from which non-infringement can plausibly be inferred.

2. NeuMoDx's inequitable conduct allegations are fatally deficient and should be dismissed. NeuMoDx alleges that BD committed inequitable conduct based solely on (i) a prosecuting attorney's remarks characterizing various proposed claim amendments and (ii) his advocacy regarding the teachings of a prior art reference. Those types of attorney argument simply cannot constitute a factual assertion giving rise to a material misrepresentation as a matter of law, particularly where there was no failure to disclose any factual information, nothing was hidden from the Patent Examiner, the claim amendments and prior art were before the Examiner, and the Examiner was free to reach his own determination about the meaning and import of the amendments and reference.

3. Even if attorney argument could theoretically constitute a factual assertion giving rise to a material misstatement (which it cannot), NeuMoDx has failed to adequately plead materiality and knowledge of materiality, and it has also not pled facts from which the Court may reasonably infer that BD (or its prosecuting attorney) acted with the requisite knowledge and intent. In short, NeuMoDx's inequitable conduct allegations fail at every level.

III. BACKGROUND AND STATEMENT OF FACTS

This patent infringement dispute arises from NeuMoDx's use and marketing HandyLab's patented technologies that were previously sold to BD, even though NeuMoDx's owners and officers had full knowledge of the patents and were in fact the very ones who transferred those technologies to BD (for a substantial sum) in the first place. D.I. 1 ¶¶ 10-13. Among the Asserted Patents is the '708 patent, which is titled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" and issued on August 16, 2011 to named inventors Kalyan Handique, Sundaresh Brahmasandra, Karthik Ganesan, and Jeff Williams. D.I. 1, Ex. 3.

A. The '708 Patent Claims Were Amended During Prosecution, And The Prosecuting Attorney Explained Those Amendments In Related Remarks

On March 17, 2010, during the prosecution of the '708 patent, BD amended the claims. A true and correct copy of the March 17, 2010 Amendment and Response to Office Action is attached as Exhibit 1.[3] The amendments changed the language of both of the pending independent claims and five of the 31 pending dependent claims. The changes were clearly identified under the header "AMENDMENTS TO THE CLAIMS" and black-lined to show the addition of new words and the deletion of original material. For example, the amendment showed the following changes to claim 1:

> 1. (Currently Amended) An apparatus, comprising:
>
> a microfluidic cartridge comprising a plurality of PCR reaction zones;
>
> a receiving bay configured to receive the ~~a~~ microfluidic cartridge;
>
> a plurality of separately controllable heat sources, each heat source thermally coupled to one or more of the plurality of PCR reaction zones and ~~at least one heat source thermally coupled to the cartridge and~~ configured to carry out PCR on a ~~microdroplet of~~ polynucleotide-containing sample[[,]] in a ~~the~~ respective PCR reaction zone ~~cartridge~~;
>
> a detector configured to detect the presence of an amplification product in the respective PCR reaction zone ~~one or more polynucleotides in the sample~~; and
>
> a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources ~~regions of the microfluidic cartridge~~.

Ex. 1 at 6.[4]

In particular, the prosecuting attorney *added* certain limitations that were not previously in the claims, namely the requirements for a "microfluidic cartridge comprising a plurality of PCR reaction zones" and a "plurality of separately controllable heat sources, each heat source thermally coupled to one or more of the plurality of PCR reaction zones." Ex. 1 at 6. The prosecuting attorney also amended the claims with respect to the description of the functionality of the "heat source[s]." The initial claims required "at least one heat source . . . configured to carry out PCR on *a*

[3] In deciding a motion to dismiss, the Court may take judicial notice of a patent's prosecution history, which is a public record. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014).

[4] Citations to "Ex. _," refer to exhibits to the Declaration of Michael J. Flynn, filed herewith.

microdroplet of polynucleotide-containing sample in the cartridge," whereas the amended claims required "each [of the plurality of] heat source[s] . . . configured to carry out PCR on *a polynucleotide-containing sample in a respective PCR reaction zone*." Ex. 1 at 6 (emphases added).

In Remarks, which were set forth in the same 15-page document as the amendments and which *immediately followed* the black-lines showing the amendments, the prosecuting attorney included a discussion of the amendments. At the conclusion of that Remarks section, the prosecuting attorney also included the following boilerplate attorney argument:

> Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

Ex. 1 at 15.

B. NeuMoDx Conclusorily Alleges Non-Infringement And Alleges Inequitable Conduct Based On Attorney Arguments During Prosecution

NeuMoDx's bare-bones counterclaim for a declaratory judgment of non-infringement does not provide a single factual allegation supporting the plausibility of its claim. Instead, NeuMoDx formulaically recites the legal standard for non-infringement by asserting that its products "do[] not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim." D.I. 15 at 15. In its amended counterclaim, NeuMoDx repeats this bare-bones counterclaim and merely adds that the asserted BD patents "are invalid and thus cannot be infringed." D.I. 15 at 15.

NeuMoDx also included inequitable conduct allegations in its amended answer and counterclaims. While NeuMoDx's allegations in that regard are vague and conclusory, NeuMoDx appears to suggest that the boilerplate language at the conclusion of the Remarks section, along with Israelsen's characterizations of a prior art reference the Examiner used to issue non-final rejections

of the '708 and '900 patents, give rise to inequitable conduct.

Specifically, NeuMoDx alleges that Israelsen, the prosecuting attorney, "removed the 'microdroplet' limitation from the claims, broadening the claim to carrying out PCR on any polynucleotide sample, not just a microdroplet." D.I. 15 at 20. NeuMoDx does not claim that the claim amendment was prohibited, unsupported, or somehow surreptitious. Instead, NeuMoDx latches on to the prosecuting attorney's boilerplate argument (quoted above) as the source of the alleged inequitable conduct. NeuMoDx alleges, without any factual support, that the statement was "intentionally incorrect and affirmatively misleading" because, in NeuMoDx's opinion, the removal of "microdroplet" was "not made to increase claim readability, improve grammar, or reduce the time and effort to understand the scope of the claim language" but instead "was an intentional and purposeful broadening of the claim beyond the scope of the invention contemplated by the inventors." D.I. 15 at 21. "Upon information and belief" NeuMoDx accuses the prosecuting attorney of "misleading representations . . . made with the intention of deceiving the USPTO." D.I. 15 at 21.

What information NeuMoDx possesses, or the basis of its belief for levying that serious charge, NeuMoDx does not say. Neither does NeuMoDx identify the source for its "information and belief [that] but for [BD's] false representations, the Examiner would have conducted additional searching given the broader scope of the claim requiring only a sample, not a microdroplet." D.I. 15 at 22. That search, NeuMoDx hypothesizes, would have led the Examiner to U.S. Patent Nos. 6,509,186 ("Zou I") and 6,762,049 ("Zou II"), but again NeuMoDx gives no explanation of how and why those references would have altered the result. D.I. 15 at 22. In its amended counterclaim, NeuMoDx merely points out that the Examiner's subsequent search queries focused on the "new limitations" that Israelsen proposed in the March 17, 2010 amendments. D.I. 15 at 22.

NeuMoDx also offers a new theory of inequitable conduct in its amended counterclaims: that Israelsen "attempted to distinguish" the claims from U.S. Patent Publication No. 2003/0199081 ("Wilding"), which the Examiner had relied on in issuing non-final rejections of certain claims of the '708 and '900 patents. D.I. 15 at 23-27. According to NeuMoDx, Israelsen argued to the Examiner that Wilding does not disclose: (1) "thermal cycling the PCR reaction zones"; (2) "a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone"; or (3) "a multilane microfluidic cartridge, each lane comprising a PCR reaction zone with heating for each reaction zone." D.I. 15 at 23, 24, 27.

NeuMoDx alleges that Israelsen "intentionally misled" the Examiner during the '708 prosecution by directing the Examiner to Figure 4 of Wilding, instead of other embodiments that allegedly disclose thermal cycling the PCR reaction zone. D.I. 15 at 23-24. Similarly, NeuMoDx alleges that Israelsen misled the Examiner by arguing that "[t]he amplification device disclosed in Wilding is a single lane (flow channel) amplification device for conducting PCR" and citing to Figures 2 and 5, because—in NeuMoDx's opinion—Wilding's specification does disclose the "multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone" limitation. D.I. 15 at 24-25. NeuMoDx also alleges that Israelsen made similar arguments regarding the scope of Wilding's disclosure during the prosecution of the '900 patent, including by arguing that Wilding only "merely describes a device with a single PCR reaction zone and an appliance with one means for heating and/or cooling the single PCR reaction zone." D.I. 15 at 26. But in NeuMoDx's view, Wilding does "disclose[] a multi-line multifluidic cartridge, each lane comprising a PCR reaction zone with heating for each reaction zone." D.I. 15 at 26-27.

IV. LEGAL STANDARD

"To survive a motion to dismiss" under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is

plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). In deciding a motion to dismiss, the court should assume the veracity of the factual allegations but must reject conclusory allegations. *LEO Pharma A/S v. Actavis Labs. UT, Inc.*, 2018 WL 1045816, at *2 (D. Del. Feb. 26, 2018) (citing *Iqbal*, 556 U.S. at 675, 678). In addition, the Court need not accept "'a legal conclusion couched as a factual allegation.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

Federal Rule of Civil Procedure 8 requires that "[a] pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), so as to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Thus, the Supreme Court has held that the Rule 8 pleading standard "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

Because a claim of unenforceability based on inequitable conduct is a litigation tactic with drastic and "far-reaching consequences," the Federal Circuit has held that the standard for establishing intent and materiality is high. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289-91 (Fed. Cir. 2011) (en banc). A claim of inequitable conduct requires the accused infringer "prove that the applicant [1] misrepresented or omitted material information [2] with the specific intent to deceive the PTO." *Id.* at 1287. Information is not material unless, "but-for" the misrepresentation or omission, "the PTO would not have allowed a claim." *Id.* at 1291. And in order to establish specific intent to deceive, an accused infringer "must prove by clear and convincing evidence that [1] the applicant knew of the reference, [2] knew that it was material, and

[3] made a deliberate decision to withhold it." *Id.* at 1290. Accordingly, even in cases of gross negligence where the patent applicant "should have known" of the materiality of the statement, this high bar is *not* met. *Id.* Furthermore, to prove specific intent to deceive, an infringer must establish that the specific intent is "the single most reasonable inference able to be drawn from the evidence," and the evidence "must be sufficient to *require* a finding of deceitful intent in light of all the circumstances." *Id.* (quotations omitted). The specific intent and materiality requirement are distinct prongs, so "a district court may not infer intent solely from materiality." *Id.*

Whether in an affirmative defense or a counterclaim, "inequitable conduct . . . must be pled with particularity" according to Federal Rule of Civil Procedure 9(b).[5] *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Systems, LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003); *see also Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013). Under Rule 9(b), to sufficiently plead inequitable conduct, "the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). In addition, the pleadings must "allege sufficient underlying facts from which a court may reasonably infer that a party acted" with specific deceptive intent to deceive. *Id.* at 1327. Inequitable conduct claims may be rejected as a matter of law upon a motion to dismiss. *Senju Pharm.*, 921 F. Supp. 2d at 308 (granting motion to dismiss counterclaim and strike affirmative defense of inequitable conduct).

V. ARGUMENT

A. NeuMoDx's Non-Infringement Counterclaim Fails To Satisfy *Twombly/Iqbal*

Following the Supreme Court's command in *Twombly* that Rule 8 "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do," 550

[5] Federal Circuit law applies to the question of whether inequitable conduct has been pleaded with particularity under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009).

U.S. at 555, courts in this District and elsewhere have faithfully applied that precedent to counterclaims for declaratory judgment of non-infringement. In *Princeton Digital Image Corp. v. Konami Digital Entertainment Inc.*, for example, this Court held that "[t]he *Twombly*/*Iqbal* standard should apply here to all aspects of the Second Counterclaim" alleging "no direct infringement." 2017 WL 239326, at *5 (D. Del. Jan. 19, 2017); *accord PetEdge, Inc. v. Marketfleet Sourcing, Inc.*, 2017 WL 2983086, at *3 (D. Mass. July 12, 2017) (holding that "where a defendant seeks to assert a viable counterclaim for non-infringement, it must do more than deny infringement").

In *Princeton Digital*, this Court granted the motion to dismiss a counterclaim of no direct infringement, agreeing that it was "merely a formulaic recitation of the elements of the claim [of non-infringement], without any supporting facts or even any identification of the products that are alleged not to infringe." 2017 WL 239326, at *5. The dismissed counterclaim merely alleged:

> 28. The allegations of Paragraphs 1-27 of the Counterclaims are incorporated by reference as if fully set forth herein.
>
> 29. Harmonix and EA have not infringed and are not infringing, either directly or indirectly, nor have the[y] contributed to or induced infringement by others, of any valid claim of the '129 patent, either literally or under the doctrine of equivalents.
>
> 30. Accordingly, Harmonix and EA are entitled to a declaratory judgment that they have not infringed and do not infringe the '129 patent.

Id. This Court found that the counterclaim "contain[ed] no facts of any kind, let alone sufficient facts to make out a plausible claim." *Id.*; *see also PetEdge*, 2017 WL 2983086, at *3 (dismissing counterclaim that "'Marketfleet has not infringed any valid and enforceable claim of the '236 patent, either literally or under the doctrine of equivalents, willfully or otherwise,' without further support" because it was "nothing more than a denial of infringement" and "fail[ed] to allege any facts to state a plausible claim for non-infringement").

NeuMoDx's conclusory non-infringement counterclaim is similarly wholly lacking in facts to support a plausible claim of non-infringement. NeuMoDx simply asserts that the "Accused

Molecular Diagnostic Products do not infringe claims, ... either directly or indirectly, because they do[] not include each and every element, either literally or by application of the doctrine of equivalents." D.I. 15 at 15. NeuMoDx's assertion is, at most, a "formulaic recitation of the elements" of non-infringement, and there are no facts supporting a plausible counterclaim. Because NeuMoDx's non-infringement counterclaim is devoid of *any* factual support, it must be dismissed under *Twombly/Iqbal*.

NeuMoDx's new allegations that BD's patents "are invalid and thus cannot be infringed" does not rescue its claim from dismissal under *Twombly/Iqbal*. D.I. 15 at 15. "Patent infringement and invalidity are two separate issues." *Hologic, Inc. v. Minerva Surgical, Inc.*, 325 F. Supp. 3d 507, 530 (D. Del. 2018) (citing *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983) ("Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question . . . without regard to its validity")). Thus, even when pled alongside plausible invalidity counterclaims, courts routinely dismiss non-infringement counterclaims supported only by invalidity allegations like those offered by NeuMoDx. *See, e.g.*, *PetEdge*, 2017 WL 2983086, at *3 (dismissing non-infringement counterclaim despite finding invalidity counterclaim adequately pled); *Beer Barrel, LLC v. Deep Wood Brew Prod., LLC*, 2016 WL 5936874, at *3-6 (D. Utah Oct. 12, 2016) (dismissing claim for declaratory judgment of non-infringement, which alleged that "Beer Barrel's Products do not and have not infringed on any valid and enforceable claim of Defendants' Patents," despite finding invalidity counterclaim plausibly alleged); *Tannerite Sports, LLC v. Jerent Enters., LLC*, 2016 WL 1737740, at *5 (D. Or. May 2, 2016) (same). NeuMoDx's invalidity counterclaims cannot, therefore, move its non-infringement counterclaim into the realm of plausibility. Accordingly, NeuMoDx's First Amended Counterclaim should be dismissed.

B. NeuMoDx's Inequitable Conduct Theories Are Fundamentally Flawed Because The Relevant Statements Are Attorney Argument, Not Factual Misrepresentations

NeuMoDx's principal inequitable conduct theory rests entirely on arguments made by the '708 and '900 patents' prosecuting attorney, Ned Israelsen. D.I. 15 at 20. NeuMoDx first alleges that "Remarks" relating to and submitted alongside clearly black-lined claim amendments were intentionally misleading because they did not specifically address the removal of the term "microdroplet" and the removal of that term allegedly "was not made to increase claim readability, improve grammar, or reduce the time and effort to understand the scope of the claim language." D.I. 15 at 20-21. Instead, NeuMoDx asserts that the removal of the word "was an intentional and purposeful broadening of the claim beyond the scope of the invention contemplated by the inventors." D.I. 15 at 21. NeuMoDx further speculates, without alleging any factual basis, that but for the statement in the Remarks, the Examiner would have conducted additional prior art searching and found art now identified by NeuMoDx. D.I. 15 at 22. NeuMoDx does not dispute, however, that the black-lined amendment to claim 1 were clear and available for the Examiner to review.

The attorney remarks upon which NeuMoDx builds its counterclaim *cannot*, as a matter of law, support a claim or defense of inequitable conduct because they are simply attorney argument and do not qualify as misrepresentations to the Examiner. NeuMoDx's counterclaim therefore must fall under Rule 12(b)(6), and NeuMoDx's affirmative defense, which incorporates the counterclaim by reference, should also be struck under Rule 12(f).

The Federal Circuit has repeatedly rejected attempts to derive claims of inequitable conduct from statements made in the "routine back and forth between examiner and applicant." *See Rothman v. Target Corp.*, 556 F.3d 1310, 1329 (Fed. Cir. 2009). That precedent recognizes the important need for a prosecuting attorney—as with any attorney—to be able to freely "present argument in favor of patentability without fear of committing inequitable conduct." *Id.* at 1328-29. Accordingly,

the Federal Circuit has treated attorney argument as "argument," rather than as representations of fact. Only the latter can form the basis for allegations of affirmative misrepresentation. For example, in *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000), the Federal Circuit reversed a bench trial determination of inequitable conduct where "the inventors merely advocated a particular interpretation of the teachings of [a prior art] article and the level of skill in the art, which the Examiner was free to accept or reject. This argument did not contain any factual assertions that could give rise to a finding of misrepresentation." *See also Masimo Corp. v. Philips Elec. N. Am. Corp.*, 2015 WL 2406061, at *12 (D. Del. May 18, 2015) (rejecting inequitable conduct claim based on prosecuting attorney's "advocacy of a claim construction position" because they "were *arguments*, not factual statements" or misrepresentations); *Cellectis S.A. v. Precision Biosciences*, 883 F. Supp. 2d 526, 535 (D. Del. 2012) (no inequitable conduct where "both examiners were free to credit or discount [applicants'] characterizations of [the prior art] in view of their own readings").

In particular, the Federal Circuit's decision in *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363 (Fed. Cir. 2008), compels dismissal of NeuMoDx's counterclaim. In *Innogenetics*, the applicant identified a prior art reference to the European Patent Office as the closest prior art. *Id.* at 1378. During the prosecution of the U.S. application, the U.S. patent attorney included the same prior art on a list of prior art references but argued those references "do not relate to the invention." *Id.* at 1379. Not only did that statement clearly contradict the applicant's prior submission to the EPO, the U.S. patent attorney later admitted that he had not actually examined the reference and his statement was boilerplate. *Id.* Nonetheless, on facts stronger than NeuMoDx alleges here, the Federal Circuit held the attorney's statement was not a material misrepresentation because it was only "boilerplate language" that "amounted to mere attorney argument and our precedent has made

clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art." *Id.* The Federal Circuit further explained that the reference was before the examiner, who was "was free to accept or reject the patentee's arguments." *Id.*; *see also Rothman*, 556 F.3d at 1329 (no inequitable conduct based on prosecuting attorney statements because the "examiner [has] the discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record").[6]

This case illustrates the exact behavior that the *en banc* Federal Circuit warned against in *Therasense*, when it criticized the "overplayed" accusation of inequitable conduct "against . . . reputable lawyers on the slenderest of grounds." 649 F.3d at 1289. NeuMoDx's approach must fail under Federal Circuit law, which shields attorney argument from frivolous charges of inequitable conduct. Here, as in *Innogenetics*, the prosecuting attorney was "free to advocate [his interpretation]" of the claim amendment to urge the Examiner to grant the amended claims. 512 F.3d at 1379. The Examiner had both the Remarks and the black-lined amendments before him, and therefore possessed full ability "to reject or accept [the] arguments based on [his] own conclusions regarding the prosecution record," *Rothman*, 556 F.3d at 1329, and evaluate the patentability of the invention in view of the prior art. As a matter of law, the prosecuting attorney's statement was advocacy, not a "factual assertion[] that could give rise to a finding of misrepresentation." *Life Techs.*, 224 F.3d at 1326; *Masimo*, 2015 WL 2406061, at *12.

NeuMoDx now alleges a second inequitable conduct theory in its amended counterclaims, namely that Israelsen, "acting on behalf of and under the direction of BD," engaged in inequitable conduct by arguing to the Examiner that Wilding did not disclose certain limitations of the '708 and

[6] NeuMoDx notes that "similar language was not used in other, later responses submitted by Mr. Israelson [sic] to the USPTO relative to the '708 patent." D.I. 15 at 21-22. That observation is irrelevant to whether the remarks are boilerplate and, in any event, ignores that the same paragraph appeared elsewhere in the file histories of the Asserted Patents. *Compare* Ex. 1 *with* Ex. 4 at 13 (identical language in prosecution of '308 patent); *and* Ex. 5 at 12 (same).

'900 patents. D.I. 15 at 23-27. That theory also has been soundly rejected by the Federal Circuit and this Court. Israelsen "merely advocated a particular interpretation of the teachings of [the prior art] . . . which the Examiner was free to accept or reject. [That] argument did not contain any factual assertions that could give rise to a finding of misrepresentation." *Life Techs.*, 224 F.3d at 1326; *see also Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) ("The mere fact that Du Pont attempted to distinguish the [claimed] process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the [claimed] process based on the art in front of him."); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007) (holding patentee's characterization of prior art reference cited by the examiner in initial rejection was "attorney argument, attempting to distinguish the claims from the prior art," and not material misrepresentation; "We therefore fail to see how the statements . . . which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact.").

This Court has faithfully applied Federal Circuit law in repeating "the uncontroversial proposition that, in arguing for patentability, patent applicants are free to distinguish their inventions from and advance their interpretations of the prior art references cited in their applications' rejections." *Cordance Corp. v. Amazon.com, Inc.*, 727 F. Supp. 2d 310, 321 (D. Del. 2010). For example, in *SunPower Corp. v. PaneClaw, Inc.*, this Court rejected an inequitable conduct claim based on the patentee's description of a prior art reference where the Examiner (1) "was aware of the [prior art reference]," (2) had initially rejected the pending claims based upon that reference, and (3) "had the expertise to examine the prior art reference and consider [patentee's] argument against the rejection." C.A. No. 12-1633, 2016 WL 5107029, at *10 (D. Del. Sept. 19, 2016) (denying defendant's motion to amend because its allegation "does not adequately plead inequitable

conduct"). NeuMoDx's inequitable conduct claim, premised on Israelsen's characterization of Wilding, presents identical circumstances: Like in *Sunpower*, Israelsen sought to distinguish Wilding after the Examiner issued non-final rejections based on that reference; additionally, there is no suggestion that the Examiner lacked the requisite expertise to examine Wilding and consider Israelsen's arguments against his non-final rejections. As *Sunpower* illustrates, Federal Circuit precedent compels dismissal of NeuMoDx's inequitable conduct argument based on characterizations of Wilding.[7]

Neither is NeuMoDx's allegation that Israelsen "intentionally misled the Examiner by directing the Examiner" to certain figures of Wilding, while not discussing other figures, sufficient to plead inequitable conduct as a matter of law. D.I. 15 at 24. *See, e.g., Advanced Ion Beam Tech., Inc. v. Varian Semiconductor Equip. Assocs.*, 721 F. Supp. 2d 62, 77 (D. Mass. 2010) ("To the extent [defendant] claims that the [patentee] chose to describe a less relevant embodiment, while remaining silent about other, more relevant embodiments, '[defendant] has provided no support for the proposition that a patent holder who discloses a reference to the PTO can be found liable for *Walker Process* fraud solely based on an alleged failure to bring every detail of the disclosed reference to the examiner's attention.'").[8] Israelsen's advocacy was mere attorney argument.

[7] *See also, e.g., Pac. Biosciences of California, Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 1353, 2019 WL 668843, at *3 (D. Del. Feb. 19, 2019) (granting motion to dismiss inequitable conduct counterclaim where defendant failed to plead "material misrepresentations regarding a prior art reference" where "it is undisputed that the Examiner had the reference . . . before her during prosecution"); *LifeScan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 379, 386 (D. Del. 2000) (holding "even if Plaintiff's characterization of the [prior art] patents was inaccurate, . . . this characterization would not rise to the level of a material misrepresentation"), *aff'd*, 13 F. App'x 940 (Fed. Cir. 2001).

[8] *Pac. Biosciences*, 2019 WL 668843, at *3 ("showing required for proving inequitable conduct and . . . for proving the fraud component of *Walker Process* liability may be nearly identical").

The Court should accordingly dismiss NeuMoDx's Third Counterclaim in its entirety.[9]

C. NeuMoDx's Inequitable Conduct Theories Should Be Dismissed Because The Elements Of Inequitable Conduct Have Not Been Pled With Particularity

Materiality. NeuMoDx's counterclaim premised on Israelsen's boilerplate Remarks during the '708 patent prosecution should also be dismissed because, although NeuMoDx has set forth a multistep materiality theory, it has failed to sufficiently plead either step with particularity. NeuMoDx's argument is not that Israelsen's statement about improving readability, grammar, and the time and effort needed to understand the claim—whether valid or not—would be material to patentability. Indeed, none of those targets are statutory bases for denying a patent. Instead, NeuMoDx theorizes that the statement somehow led the Examiner not to conduct prior art searches that would have led to material information. This materiality argument is based on two conclusory assumptions: (1) the Examiner would have conducted more searches that would have uncovered different prior art, and (2) that prior art would have led to the Examiner rejecting the claim. D.I. 15 at 22.

In *Exergen*, the Federal Circuit explained that, in order to meet the Rule 9(b) particularity standard, a pleading must identify the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." 575 F.3d at 1327. NeuMoDx's allegations fail the *Exergen* standard in a myriad of ways. NeuMoDx has failed to allege with particularity "what" other searches the Examiner would have run or "how" those different searches would have found the prior art that it now cites. Instead, NeuMoDx relies on conclusory allegations that are contradicted by the only record evidence it points to—the prosecution history—which suggests that the term "microdroplet" was not material to the Examiner's searches. For example, the

[9] NeuMoDx alleges that the '900 patent is unenforceable due to "the doctrine of infectious unenforceability or fruit of the poisonous tree." D.I. 15 at 25. This argument fails because Israelsen did not engage in inequitable conduct with respect to the '708 patent, as explained above. *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1375 (Fed. Cir. 2007). Moreover, there are no factual allegations explaining how that doctrine would be applicable here.

Examiner conducted several prior art searches before the March 17, 2010 amendment. None of these searches were limited by the term "microdroplet." *See* Ex. 2 at 17-23. Nor were the Examiner's prior art searches conducted after the March 17, 2010 amendment—which NeuMoDx cites in its amended counterclaim—limited by the term "microdroplet." *See* Ex. 3 at 19-21; D.I. 15 at 22. Even so, the Examiner did not find the prior art NeuMoDx alleges would have been found.

Similarly, NeuMoDx has not alleged with particularity why the claims of the '708 patent would have been rejected in light of the prior art that it cites. Its pleading was required to "identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found—i.e., the 'what' and 'where' of the material omissions." *Exergen*, 575 F.3d at 1329. Rather than attempt to meet this burden, NeuMoDx has generally alleged that "the Examiner would have found a number of other prior art references that disclosed the elements of the claims of the '708 patent, but not a microdroplet, including, for example Zou I, U.S. Patent No. 6,509,186 and Zou II, U.S. Patent No. 6,762,049." D.I. 15 at 22. That allegation fails to explain "what" specifically is disclosed by Zou I and Zou II, and "where"—factual deficiencies that are "fatal" under Rule 9(b). *See Exergen*, 575 F.3d at 1330. These fatal defects also demonstrate that NeuMoDx likewise failed to plead sufficient facts supporting the "but-for materiality" required by *Therasense*. 649 F.3d at 1291.

Intent To Deceive. NeuMoDx has also failed to plead definite facts to support its claim that there was a specific intent to deceive the PTO. It has alleged, at most: (1) BD's statement was incorrect and (2) that it "buried" the elimination of the microdroplet limitation with a number of other claim amendments. D.I. 15 at 22. Even accepting NeuMoDx's allegations as true, a court could not reasonably infer that BD knew the statement was false and had a specific deceptive intent because NeuMoDx has not provided a factual basis for its bald accusations that, "[u]pon information

and belief, Israelson's false and misleading representations, while acting on behalf of and under the direction of BD, to the Patent Office were made with the intention of deceiving the USPTO." D.I. 15 at 21; *see Exergen*, 575 F.3d at 1330-31 (finding insufficient that "[d]eceptive intent . . . was pleaded solely on 'information and belief'" (brackets omitted)).

Moreover, even misstatements in attorney argument are immunized from accusations of deceptive intent where the information is openly provided to the Examiner, making clear the patentee's intent. *See Cornell Univ. v. Illumina, Inc.*, 2017 WL 89165 (D. Del. Jan. 10, 2017) (holding it was not reasonable to infer from an "inartful" statement in a declaration that applicants intended to mislead the PTO where the actual language of the amendment the declaration supported made applicants' intention clear). Furthermore, as discussed above, the Federal Circuit has made clear that attorney argument characterizing the applicants' claims or the prior art does not constitute "factual assertions that could give rise to a finding of misrepresentation." *Life Techs.*, 224 F.3d at 1326; *Innogenetics*, 512 F.3d at 1379. The fact that, years later, NeuMoDx can pluck an attorney's argumentative characterization out of the prosecution history and attribute to it some malicious purpose that is plainly inconsistent with the open claim amendment that it supports, does not provide a basis to infer deceptive intent.

NeuMoDx's suggestion that BD "buried" the elimination of the microdroplet limitation to hide it from the Examiner is likewise facially flawed. This Court has rejected the notion that "burying" a reference that is actually disclosed can constitute inequitable conduct. *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 358 (D. Del. 2009) ("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner."). Notably here, rather than hiding a statement or document among hundreds or thousands of pages of varying degrees of relevance, BD is alleged to have hidden a claim amendment in a four-page, double-spaced document

by clearly blacklining the language of claim 1 under the header: "AMENDMENTS TO THE CLAIMS." Because the claim amendment was cited to the Examiner, there can be no inequitable conduct found on the basis of "burying." *See id.* at 358.

Knowledge of Materiality. Finally, NeuMoDx does not even attempt to address knowledge of materiality. *See Therasense*, 649 F.3d at 1290 (specific deceptive intent requires "kn[o]w[ledge] that it was material"). NeuMoDx fails to allege that any individual *knew* that the string of interdependent events NeuMoDx now hypothesizes would somehow come to pass, would somehow be material and/or would somehow prevent a finding of unpatentability. Equally importantly, NeuMoDx does not include any facts allowing a court to infer any of that plausibly happened.

NeuMoDx's second inequitable conduct theory as to Israelsen's characterizations of the Wilding reference during the '708 and '900 patent prosecutions suffers from the same flaws, and should also be rejected.[10] Accordingly, NeuMoDx's Third Counterclaim should be dismissed. Like counterclaims, affirmative defenses of inequitable conduct both need to be plead with particularity under Rule 9(b), and accordingly they rise and fall together. *Senju Pharm.*, 921 F. Supp. 2d at 306. NeuMoDx's affirmative defense falls with its counterclaim and should, therefore, be struck under Rule 12(f).

VI. CONCLUSION

For all of the above reasons, the motion should be granted.

[10] Even if Israelsen's advocacy could qualify as material misrepresentations as a matter of law (which they cannot, *see supra* Section V.B), NeuMoDx's claims further fail because there are no allegations of knowledge of materiality and a deliberate decision to withhold information, let alone facts from which an intent to deceive could be inferred. *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1377 (Fed. Cir. 2012). There was no showing that Israelsen knew that any descriptions of Wilding that he omitted were material and would have led to a rejection, and that he knowingly withheld any information.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Michael J. Flynn

Jack B. Blumenfeld (#1014)
Michael J. Flynn (#5333)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mflynn@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

William G. McElwain
David P. Yin
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Omar A. Khan
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

October 25, 2019

CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on October 25, 2019, upon the following in the manner indicated:

Brian E. Farnan, Esquire — *VIA ELECTRONIC MAIL*
Michael J. Farnan, Esquire
FARNAN LLP
919 North Market Street, 12th Floor
Wilmington, DE 19801
Attorneys for Defendant

James K. Cleland, Esquire — *VIA ELECTRONIC MAIL*
Joshua Ney, Esquire
BRINKS GILSON & LIONE
524 S. Main Street, Suite 200
Ann Arbor, MI 48104
Attorneys for Defendant

Andrea Shoffstall, Esquire — *VIA ELECTRONIC MAIL*
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive, Suite 3600
Chicago, IL 60611
Attorneys for Defendant

/s/ Michael J. Flynn
Michael J. Flynn (#5333)